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| Michael I Stewart Sim & McBurney 6th Floor 330 University Avenue Toronto, M5G 1R7 CANADA | | | EXAMINER TSAY, MARSHA M | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/517,277

Applicant(s)

MILANOVA ET AL.

Examiner

Marsha M. Tsay

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3, 4, 11-16, 20-24, 26-28, 32-34, 36-43, 49 and 51-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3, 4, 11-16, 20-24, 26-28, 32-34, 36-43, 49 and 51-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-646)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

This Office action is in response to Applicants' remarks received April 9, 2010.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Claims 1-2, 5-10, 17-19, 25, 29-31, 35, 44-48, 50 are canceled. Claims 3-4, 11-16, 20-24, 26-28, 32-34, 36-43, 49, 51-53 are currently under examination.

Priority: The request for priority to provisional application 60/401782, filed August 8, 2002, and provisional application 60/390126, filed June 21, 2002, is acknowledged.

Objections and Rejections

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-4, 11-16, 24, 26-28, 32-34, 36-43, 49, 51-53 are rejected under 35 U.S.C. 103(a) as being obvious over Murray (US 6005076; IDS 07.25.06, previously cited) in view of Rossi et al. (Lebensmittel-Wissenschaft Und-Technologie 1982 Istituto Di Technologie Alimentari, Univ. Degli Studi Di Milano, Via Celoria 2, 20133, Milan Italy 15(5): 309-312; IDS 07.25.06; previously cited).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(1)(1) and § 706.02(1)(2).

In Example 3 (col. 7, lines 60-67), Murray discloses a process of initially preparing a protein isolate using a meal prepared from the cold pressing of canola seeds to give a consistency similar to canola meal, followed by a protein extraction and recovery process (as described in Example 2). According to Murray, the "canola meal" may be any canola meal resulting from the removal of canola oil from canola seed (col. 2-3, lines 66-2). In Example 2, Murray discloses that meal from rapeseed containing 32.5% protein, 10.1% fat and 6.1% moisture was extracted with an aqueous salt solution and agitation (col. 7 lines 37-40). It would be reasonable for one of ordinary skill to recognize that the initial rapeseed meal having a moisture content of 6.1% would be essentially a dried meal product that is desolventized. The aqueous meal/salt solution

was mixed for 2 hours at 25°C to remove residual meal and then chilled to 8°C followed by centrifugation (col. 7 lines 5, 40-43). Murray discloses the aqueous salt solution with an ionic strength value of less than 0.8 and within the range of 0.3 to 0.6 (col. 8, lines 62-63), a pH range of 5.3 to 6.2 (col. 8, line 66-67), and wherein the aqueous protein solution has a concentration of about 10-100 g/L of protein (col. 9, lines 1-3). In addition, Murray discloses that the formation of protein isolates into micelles is achieved optimally at pH values of 5.3 to 6.2 (col. 3, lines 46-50). After separating the aqueous protein solution from the residual oil seed meal, Murray discloses a process step for increasing the protein concentration using a selective membrane technique, diluting the concentrated protein solution by 15 fold at 6 ° C to form protein micelles, settling the protein micelles, and recovering the protein mass to provide a dried proteinaceous powder having a protein content of at least 90 wt % (col. 7, lines 12-30, col. 8, lines 31-61). Murray does not explicitly teach a desolventized oil seed meal under vacuum (i.e., the steps of 3(b) and 3(c)) or a continuous mode of operation.

Rossi et al. disclose that to obtain a protein meal, an initial oil-extraction process is used to obtain a "cake" that is rich in protein. Rossi et al. further disclose a desolventizing under vacuum technology can be performed at 40°C of said cake to obtain a protein meal (p. 309, 310 Figure 1, p. 311 column 2).

The instant claims are essentially drawn to a process of preparing a protein isolate comprising processing a desolventized oil seed meal. The desolventized oil seed meal is obtained by the process described in claims 3(a)-3(d). The actual process to recover protein isolate from the desolventized oil seed meal is described in claims 3(e)-3(j).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Murray of obtaining a protein isolate by first crushing canola seeds (claim 3a), substituting the oil-extraction process (claim 3b, 3c) and desolventizing under vacuum process (claim 3d) of Rossi et al. to obtain a desolventized oil seed meal and then processing said desolventized oil seed meal to obtain a protein isolate by extracting said desolventized oil seed meal to cause solubilization and to form an aqueous protein solution having a pH of about 5-6.8, maintain the aqueous solution at an ionic strength and pH range that is suitable for the formation of protein micelles (claims 3-4, 11-16, 24, 32-34, 36-37), increase the protein concentration (claim 3), dilute the concentrated protein solution to induce the formation of protein micelles (claim 3-4, 11-16, 24, 32-34, 36-37), settle the protein micelles, and recover the protein micelles to make a dry proteinaceous powder having a protein content of at least 90 wt % (claim 3-4) because Murray provides and suggests motivation for a method of preparing a protein isolate from a desolventized oil seed meal and Rossi et al. teach a desolventized oil seed meal under vacuum.

Murray does not specifically disclose that steps (e) to (j) of claims 3-4 are effected in a semi-continuous or continuous mode of operation.

However, it would have been obvious to one of ordinary skill in the art at the time of the invention, for the steps of (e) through (j) of the process of making a canola protein isolates as taught by Murray, to have been effected in a continuous mode of operation in order to increase the efficiency and overall production capacity of the system. One of ordinary skill in the art would have been motivated to make the process of Murray run in a continuous or semi-continuous mode

in order to achieve the maximum efficiency of the production system, thereby increasing production of said protein isolate and increasing financial returns.

Further, the court has held that a claimed continuous operation would have been obvious in light of the batch process of the prior art. *In re Dilnot*, 319 F.2d 188, 138 USPQ 248 (CCPA 1963). See also MPEP 2144.04.

Regarding claims 24, 42-43 (i.e. salt is subsequently added to the resulting aqueous protein solution to provide an aqueous protein solution having an ionic strength of at least 0.10), it should be noted since Murray discloses that extracting canola oil seed meal is effected using an aqueous salt solution having an ionic strength of at least 0.2 and a pH of about 5-6 (col. 3 lines 9-11, lines 40-41), it is believed that salt is added to the water at some point during the extraction process. Further, it is known that selection of any order of mixing ingredient is *prima facie* obvious in the absence of new or unexpected results. *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results); *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930). See also MPEP 2144.04. In this instance, it would be reasonable for one ordinary skill to know that the addition of salt to an aqueous solution would also require a dialyzing step in order to eliminate the salt from the concentration protein solution (claims 42-43).

Regarding claim 26, 49 (i.e. said concentration step is effected by ultrafiltration), as noted above, Murray discloses a process step for increasing the protein concentration using a selective membrane technique. It would be reasonable for one of ordinary skill to know that an ultrafiltration technique is within the scope of a selective membrane technique. The normal desire of scientists to improve upon what is already generally known provides the motivation to

determine which specific membrane should be used to produce a protein isolate which will have the highest protein content, i.e. greater than 100 g/L, 200 g/L, etc.

Regarding claims 27-28 (i.e., said concentrated protein solution is warmed to a temperature of at least 20°C), Murray discloses the concentration of the protein solution may be effected at any convenient temperature, i.e. 20°C to 45°C (col. 4 lines 66-67 to col. 5 lines 1-5). Therefore, it would be reasonable for one of ordinary skill to be motivated to determine which conditions will yield the highest protein concentration in order to obtain a protein isolate with the highest protein content.

Regarding claims 38-41, 51-53 (i.e., recovering additional quantities of protein isolate from the supernatant by concentrating the supernatant to a protein concentration of about 100 to 400 g/L), as noted above, Murray discloses increasing the protein concentration; therefore, it would be reasonable for one of ordinary skill to determine at which protein concentration the supernatant should be at (i.e. greater than 100 g/L, 200 g/L, etc.) in order to recover a protein micellar mass that will yield a protein isolate with the highest protein content. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP 2144.05. Further, it is known that selection of any order of mixing ingredient is *prima facie* obvious in the absence of new or unexpected results. *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is *prima facie* obvious in the absence of new or

unexpected results); *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930). See also MPEP 2144.04.

Applicants have currently amended the claims to recite a process of preparing a canola protein isolate. Applicants' arguments are believed to be essentially directed to the Rossi et al. reference since the Rossi et al. reference has been used to remedy the shortcomings of Murray et al. Therefore, Applicants' arguments have been summarized herein and are mainly directed to the Rossi et al. reference.

In their remarks, Applicants assert that (1) Murray et al. do not disclose or suggest the combination of steps (a) to (d) of the independent claims with steps (e) to (j) of those claims. It is conceded that the Murray et al. reference describes instant steps (e) to (j) of the independent claims. The Examiner attempts to remedy the shortcomings of Murray et al. by reference to Rossi et al. Rossi et al. is concerned with a procedure of obtaining a food grade protein meal from defatted sunflower. (2) To achieve the goal of Rossi et al. (i.e. a food-grade meal), it is necessary to not only desolventize the sunflower meal under vacuum, but also to effect a sieving operation on the meal. As already noted, the goal of the present invention is different, namely to obtain a canola protein isolate, which does not require any sieving operation to be carried out on the canola oil seed meal. Applicants' claims are directed to the formation of a canola protein isolate by the processing of canola oil seeds.

Applicant's arguments have been fully considered but they are not persuasive.

(1) Response: Firstly, it should be noted that Murray discloses that his process can be applied to other oil seeds (i.e. soybeans), and not just to canola seed. It is well known in the art

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that soybeans, canola seeds, and sunflower seeds are all oil-bearing seeds that can be refined and de-oiled (evidenced by Dahlke 1998 Chem Eng Technol 21(3): 278-281). Therefore, it would be reasonable for one of ordinary skill to know that the process of Murray is applicable to oil-bearing seeds in general, including sunflower, soybean, and canola. Murray discloses that the seed meal (the de-oiled seed) results from the removal of oil from the seed, for example by hot hexane extraction or cold oil extrusion methods (col. 2 line 66 to col. 3 line 3). Rossi et al. disclose that traditional oil extraction techniques do not provide cake (or meal) suitable for protein nutrition (Rossi et al. p. 309). The seed meal has poor nutritional qualities because of high fiber content and may suffer from heat damage during processing. Therefore, Rossi et al. have disclosed that using a low-temperature desolventizer operating under vacuum can produce a seed meal that is suitable for nutritional consumption and of high structural quality (Rossi et al. p. 309). Since Murray discloses a process for obtaining a protein isolate from the meal of an oil-bearing seed and Rossi et al. further disclose the advantages of using a low-temperature desolventizer operating under vacuum to obtain meal from an oil-bearing seed, it would be reasonable for one of ordinary skill to substitute the oil extraction and low-temperature desolventizing under vacuum step of Rossi et al. for the general oil removing steps disclosed by Murray. Since canola seeds and sunflower seeds are both oil-bearing seeds, it would be reasonable for one of ordinary skill to know that the steps used to process any oil-bearing seed would overlap in scope and that the steps used to process one type of oil-bearing seed would be applicable to another oil-bearing seed since said oil-bearing seeds have always been processed to obtain oil, meal, and protein.

(2) Response: It should be noted that the use of open claim language “comprising” allows for the inclusion of additional steps and components in the claims. Therefore, even if Rossi et al. disclose an additional sieving operation to be carried out on the oil seed meal, said sieving operation does not interfere with obtaining the oil seed meal.

Regarding Applicants’ remarks that the goal of the present invention is different, it should be noted that the instant process recites preparing canola protein isolate from canola oil seed meal. Murray discloses that to obtain a canola protein isolate, the canola seeds have to be treated in order to obtain canola seed meal. Since Rossi et al. disclose the advantages of preparing a seed meal, it would be reasonable for one of ordinary skill to apply the teachings of Rossi et al. to obtain a seed meal that can then be further processed downstream to obtain a protein isolate. One of ordinary skill would know that the seed meal is the starting material from which the protein isolate is obtained from and since Rossi et al. disclose an advantage to obtaining seed meal by using a low-temperature desolventizer operating under vacuum step versus the general steps known in the art, then it would be reasonable for one of ordinary skill to combine the teachings of Murray and Rossi et al. for obtaining protein isolates from an oil-bearing seed, i.e. canola, soybean, etc.

See also the response of (1).

Additionally, regarding Applicants remaining remarks directed towards the independent and dependent claims 24, 42-43, 26, 49, 27-28, 38-41, 51-53, since said independent claims recite similar steps, the reasons for maintaining the 103(a) rejection for these claims are the same as noted in the responses of (1) and (2), since the Murray and Rosi et al. references have been applied as 103(a) references over the claims.

Claims 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murray (US 6005076; IDS, previously cited) in view of Rossi et al. (Lebensmittel-Wissenschaft Und-Technologie 1982 Istituto Di Technologie Alimentari, Univ. Degli Studi Di Milano, Via Celoria 2, 20133, Milan Italy 15(5): 309-312; IDS 07.25.06; previously cited) in view of Cook et al. (US 5254673; previously cited). The teachings of Murray in view of Rossi et al. are outlined above. Murray discloses that the presence of fat in protein production can lead to discoloration resulting from the co-processing of pigments in the meal with the fat.

Cook et al. disclose a process for zein protein purification from corn meal. Cook et al. disclose that activated carbon powder can be used to further purify said protein from meal (col. 9 example 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Murray in view of Rossi et al. by adding in the step of incorporating activated carbon powder as suggested by Cook et al. in order to obtain a protein isolate from the canola seed meal (claims 20-23). The motivation to do so is given by Cook et al. which disclose that activated carbon powder can be incorporated into a protein processing method in order to better purify the protein isolate that is obtained from a seed meal.

In their remarks, Applicants assert that Cook et al. is concerned with zein and not with canola. While Cook et al. describe that activated carbon can be incorporated into a protein processing method for pigment removal, it is submitted that this teaching does not disclose or suggest effecting a pigment removal step on the aqueous canola protein solution formed in

Murray. In addition, the Cook et al. reference does not disclose or suggest a pigment removal step using diafiltration as specifically claimed in claim 21.

Applicant's arguments have been fully considered but they are not persuasive.

Response: Both the instant process and the Cook et al. process are drawn to obtaining a protein from meal. Since Cook et al. disclose that activated carbon can be used in a protein processing method for pigment removal, it would be reasonable for one of ordinary skill to extend the pigment removal step of Cook et al. to Murray because Murray discloses a process for obtaining protein from meal. One of ordinary skill would know that the pigment removal step of Cook et al. can logically be extended for use in other protein processing methods that are used to obtain protein from meal because the purpose of the process is the same, i.e. obtaining protein from meal despite the multiple steps that are involved.

Regarding the diafiltration step, it should be noted that since Murray discloses a selective membrane technique step, said selective membrane technique step would effect a pigment removal step even if not explicitly stated by Murray.

For at least these reasons, the Murray and Cook et al. references are maintained.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

July 3, 2010

M. Tsay
Art Unit 1656

/Manjunath N. Rao /
Supervisory Patent Examiner, Art Unit 1656